USSN: 09/754,094

Filing date: January 3, 2001

Amendment and Response to Restriction Requirement

Page 4 of 9

95

(Amended) The method of claim 39, wherein the microcatheter system or flexible cannula remains within the retinal vein during the infusion without an external holding device for a period of time of at least 5 minutes.

RESPONSE TO RESTRICTION REQUIREMENT

Applicants respond as follows to the Restriction/Election of Species Requirement as set forth in the Office Action dated August 27, 2002.

Applicants conditionally elect Group I, claims 1 to 35, drawn to a microcatheter system, with traverse. The Examiner has stated that method claims (claims 36-55) represent a distinct invention because the process as claimed can be practiced by another materially different apparatus or by hand, or the apparatus as claimed can be used to practice another and materially different process.

Applicants respectfully request that the requirement be reconsidered and withdrawn. Claim 36 has been cancelled and all of the process claims now specifically refer to the use of the apparatus of any of claims 1 to 3. Therefore, the process as claimed cannot be practiced by a materially different apparatus or by hand. Further, the apparatus as claimed, cannot fairly be said to be used in a process other than retinal vein catheterization.

The claims have been further amended merely to remove improper multiple dependencies. No new matter is added by these amendments. Applicants note that the Application, as filed, included claims 1-36 and 39-57. Due to a typographical error, no claims were numbered 37 or 38.

In review of the above arguments, Applicants therefore respectfully request that the Examiner rejoin the methods recited in claims 39-55, and examine claims 1-35 and 39-55. However, in the event that the claims are not rejoined, Applicants elect Group I for further

USSN: 09/754,094

Filing date: January 3, 2001

Amendment and Response to Restriction Requirement

Page 5 of 9

examination without prejudice to pursuing the method claims or related claims in a continuing or other related application.

The Examiner has additionally imposed an election of species requirement. The Examiner states that:

In addition to the restriction above, this application contains claims directed to the following patentably distinct species of the claimed invention and a further election of species is required for either group selected above:

- a. Figs. 1 and 6-11
- b. Figs 2 and 6-11,
- c. Figs. 3 and 6-11, and
- d. Figs. 4 and 6-11.

Applicants traverse the requirement, but elect Species A, corresponding to Figures 1 and 6-11, without prejudice to pursuing embodiments corresponding to the remaining Figures in a continuing or other related application.

Applicants respectfully submit that the present invention is a surgical device 1 that comprises a cannula 2 having a proximal end 4 and a distal end 6. The cannula 2 is designed for insertion into main tributaries of human retinal veins. Fig. 1 depicts an isometric view of the surgical device. As set out by Applicants:

Due to the flexible, delicate nature of the cannula 2, grasping the cannula 2 directly, with forceps or similar grasping means, during insertion and positioning of the cannula 2 within the retinal vein may crimp and damage the cannula 2, which would limit or even prevent the flow of solution through the cannula 2. Thus, to facilitate insertion and manipulation of the cannula 2 within the eye, the surgical device 1 of the present invention may further comprise various protection means.

Page 13, lines 19-25.

Thus, Fig. 1 shows the overall general features of the surgical device 1. Figures 2-4 show examples of the protection means, which may be one or more small wing-like extensions 26 mounted on the outer surface of the cannula 2 (Fig. 2), a metal portion 28

USSN: 09/754,094

Filing date: January 3, 2001

Amendment and Response to Restriction Requirement

Page 6 of 9

mounted on the cannula 2 which could be grasped by forceps or by an electromagnet 30 (Fig. 3), or a wire 30 mounted on the cannula 2 which could be grasped by forceps or similar grasping means (Fig. 4).

Applicants respectfully submit that Figs. 1-4 do **not** describe patentably distinct species, but, rather, Fig. 1 shows a surgical device and Figs. 2-4 merely show examples of protection means that may be mounted on the surgical device. As such, Applicants respectfully request that the requirement be reconsidered and withdrawn.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105**.

CONCLUSION

Applicant submits that all claims are allowable as written and respectfully requests early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned agent of record.

Date: October 28 2002

By:

isa Swiszcz Hazzard (Reg. No. 44,36

Diagne Rees, Ph.D. (Reg. No.45,28)

EDWARDS & ANGELL, LLP

PO BOX 9169

Respectfully submitted,

Boston, MA 02209

Telephone: 1-617-439-4444

Fax: 1-617-439-4170 Customer No: 21,874

USSN: 09/754,094

Filing date: January 3, 2001

Amendment and Response to Restriction Requirement

Page 7 of 9

Marked-Up Version of Claims Showing Changes Made

- 5. (Amended) The microcatheter system of any one of claims 1 through 3[4], wherein the microcatheter system comprises a flexible cannula for insertion into a retinal vein [lumnen] lumen, the flexible cannula having a proximal end and a distal end and the distal end is sharp and rigid for puncturing the retinal vein lumen.
- 6. (Amended) The microcatheter system of [any one of claims 1 through] <u>claim</u> 5, wherein the distal end has a beveled ramp-like shape.
- 7. (Amended) The microcatheter system of [any one of claims 1 through] <u>claim</u> 6, wherein the ramp-like distal end forms an angle of about 30°.
- 8. (Amended) The microcatheter system of any one of claims 1 through $\underline{3}$ [7], wherein the flexible cannula is fabricated of polyimide.
- 9. (Amended) The microcatheter system of any one of claims 1 through $\underline{3}$ [8], wherein the flexible cannula has an outer diameter less than about 100 \square m.
- 12. (Amended) The microcatheter system of any one of claims 1 through 3 [11], further comprising a second cannula having a larger diameter than the flexible cannula.
- 19. (Amended) The microcatheter system of any one of claims 1 through 3 [18], further comprising a modified microcannula system in which the flexible cannula and second cannula are mounted.
- 24. (Amended) The microcatheter system of [any one of] claim[s 1 through 2]12, wherein the flexible cannula is illuminated for enhanced visibility.

USSN: 09/754,094

Filing date: January 3, 2001

Amendment and Response to Restriction Requirement

Page 8 of 9

- 25. [Amended] The microcatheter system of any one of claims 1 through 3 [24] wherein the microcatheter system or flexible cannula remains within the retinal vein during the infusion without an external holding device for a period of time of at least 5 minutes.
- 35. (Amended) A medical device kit, comprising one or more of the microcatheter systems of any one of claims 1 through 3[3].
- 40. (Amended) The method of claim[s 38 or] 39, wherein solution is infused at a flow rate of at least about 0.2 cc/min.
- 41. (Amended) The method of [any one of claims 38 through 40] claim 39, further comprising inserting a metal cannula into an incision in the eye prior to inserting the microcatheter system into the eye, whereby the microcatheter system is inserted into the eye through the metal cannula.
- 43. (Amended) The method of [any one of claims] claim <u>39</u> [36 through 42], further comprising the step of making four sclerotomies in the eye, whereby two microforceps are inserted in two of the sclerotomies and the microcatheter system is inserted into the eye through the fourth sclerotomy.
- (Amended). The method of [any one of claims] <u>claim</u> 43 [through 45], further comprising the steps of passing the microcatheter system back and forth between the microforceps to position the microcatheter system so that the distal end of the flexible cannula is approximately parallel to the retinal vein
- 47. (Amended) The method of [any one of claims] <u>claim 39</u> [36 through 46], wherein the microcatheter system further comprises a second cannula having a larger diameter than the flexible cannula, the second cannula having a proximal end and

USSN: 09/754,094

Filing date: January 3, 2001

Amendment and Response to Restriction Requirement

Page 9 of 9

a distal end, whereby a portion of the flexible cannula is housed within the distal end of the second cannula.

49. (Amended) The method of [any one of claims] <u>claim 39</u> [36 through 48], wherein the microcatheter system or flexible cannula remains within the retinal vein during the infusion without an external holding device for a period of time of at least 5 minutes.

#316567